

**Participants' Views of Delayed Consent for a Randomised
Controlled Trial in Intensive Care**

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Certificate of Authorship/Originality

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

Signature of Student

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Table of Contents

<i>Certificate of Authorship/Originality</i>	<i>ii</i>
<i>Acknowledgements</i>	<i>iii</i>
<i>List of Figures</i>	<i>vi</i>
<i>List of Tables.....</i>	<i>vi</i>
<i>Abstract.....</i>	<i>vii</i>
<i>Chapter One: Background and Literature Review</i>	<i>1</i>
1.1 Introduction	1
1.2 Consent for Research in Intensive Care	4
1.3 Alternative Methods of Consent for Research	6
Substitute decision maker consent.....	6
Waiver of consent.....	6
Delayed consent	7
1.4 Potential Problems with the Substitute Decision Maker	8
Authorisation of the substitute decision maker	8
Decisional capacity of the substitute decision maker	9
Accuracy of the substitute decision maker	10
1.5 Potential Problems with Delayed or Deferred Consent.....	12
1.6 Preferences for Informed Consent	12
Opinions of enrolment using delayed consent	14
1.7 Summary of Findings Located in the Literature.....	14
1.8 Outline of the Thesis.....	15
1.9 Study Aims	16
<i>Chapter Two: Methods</i>	<i>17</i>
2.1 Introduction	17
2.2 Research Design.....	17
2.3 Setting.....	18
2.4 Sample	18
Inclusion criteria	18
Exclusion criteria	18
2.5 Cognitive Assessment	18
2.6 Questionnaire	19
Pilot testing	19
2.7 Recruitment Procedures	20
Follow up procedure	21
2.8 Data Collection.....	22
Quality of secondary data sources.....	22
2.9 Data Entry	23
2.10 Data Analysis.....	23
2.11 Minimisation of Personal Bias	24
2.12 Ethical Considerations	25
Emotional wellbeing of study participants	25
<i>Chapter Three: Results.....</i>	<i>26</i>
3.1 Introduction	26
3.2 Participants	26
3.3 Characteristics of Participants in the NICE-SUGAR study at the RNSH	28
3.4 Characteristics of Respondents	30
3.5 Opinion of Delayed Consent	33
3.6 Thoughts about Enrolment in the NICE-SUGAR Study.....	34
3.7 Participation will Help Others.....	35

3.8 Preferences for Decision Makers	36
3.9 Decisions Regarding Consent.....	38
3.10 Would have Provided Consent Before Enrolment?	40
3.11 Further Comments.....	42
3.13 Conclusion	43
Chapter Four: Discussion and Conclusion.....	44
4.1 Introduction and Summary of Major Findings.....	44
4.2 Interpretation of the Results	44
4.3 Strengths and Limitations of the Study	48
4.4 Implications for Practice	51
4.5 Future Recommendations	52
4.6 Conclusion	52
References.....	54
Appendix A Questionnaire	59
Appendix B Telephone Transcript	63
Appendix C Cover Letters	65
Appendix D Summary of the NICE-SUGAR Study Results	69
Appendix E Data Collection Forms.....	70
Appendix F HREC Approval Letters	74
Appendix G The NICE-SUGAR Study Investigators	79

List of Figures

Figure 1	<i>Screening and enrolment.....</i>	27
Figure 2	<i>Box plot summarising respondents' feelings about enrolment using delayed consent.....</i>	33
Figure 3	<i>Bar graph showing opinions of participation in the NICE-SUGAR Study helping future patients.....</i>	35
Figure 4	<i>Bar graph showing opinions about the selection of substitute decision maker.....</i>	38
Figure 5	<i>Bar graph showing agreement with the decision made by the substitute decision maker.....</i>	39
Figure 6	<i>Bar graph showing contentment with the decision made by the substitute decision maker.....</i>	39

List of Tables

Table 1	<i>Characteristics of participants in the NICE-SUGAR study.....</i>	29
Table 2	<i>Demographic characteristics of respondents.....</i>	31
Table 3	<i>Characteristics of delayed consent for respondents.....</i>	32
Table 4	<i>Content analysis for the open ended question “What were your thoughts about enrolment in NICE?”</i>	34
Table 5	<i>First preference for a person or organisation for decision making.....</i>	36
Table 6	<i>Characteristics of respondents who preferred “The person who consented on my behalf for the NICE study”</i>	37
Table 7	<i>Association of respondent characteristics with willingness to participate in the NICE-SUGAR study.....</i>	41
Table 8	<i>Content analysis for the open ended question “Is there anything else regarding your participation in the NICE study you wanted to raise?”</i>	42

Abstract

Each year many people experience critical illness and require a stay in an intensive care unit. Critical illness has a high mortality, making evaluation of therapies a priority for research in this area. Research conducted in the critical care environment is difficult with respect to obtaining first person informed consent. Patients who are critically ill have diminished capacity for decision making and consequently they are rarely able to provide informed consent before enrolment in a clinical trial. In Australia, critically ill patients are enrolled into clinical trials using delayed consent. However, there is a paucity of research on the opinion of clinical trial participants about consent obtained following enrolment.

The aim of this study was to determine the opinion of participants enrolled in the NICE-SUGAR study, under the provision for delayed consent, of the delayed consent process. A secondary aim was to investigate their opinions of third party consent and their preferences for decision makers. Former ICU patients who were enrolled in the NICE-SUGAR study at the Royal North Shore Hospital (RNSH) with delayed consent, who were cognitively intact when screened, and were judged to have sufficient proficiency in the English language, were contacted and invited to participate in this study. Willing participants completed a questionnaire regarding their opinion of the delayed consent process. The questionnaire was developed for this study and contained fixed response and open ended questions.

There were 634 participants in the NICE-SUGAR study at the RNSH, 256 of these former ICU patients were contacted and responses were received from 210 (response rate 82%). Participants were 37.6% female with mean \pm SD age of 61 \pm 16 and APACHE II scores of 18 \pm 6.79. Delayed consent was obtained from participants (57/210; 27.1%) and the substitute decision maker (152/210; 72.4%). Most respondents (195/204; 95.6%) reported they would have consented to participate in NICE-SUGAR if asked before enrolment. Most respondents (163/198; 82.3%), ranked first (mean=1.49) “the person who consented on their behalf for the NICE Study” as most preferred to make decisions on their behalf. Most (177/202; 87.6%) agreed with the decision made by their relative/friend.

In conclusion, most former ICU patients who had been enrolled in the NICE-SUGAR study from the RNSH with delayed consent, would have provided consent to participate had they been capable. Furthermore, most respondents agreed with the decision made by the substitute decision maker.